

cellulose, hydroxypropyl methyl cellulose acetate succinate, hydroxypropyl methyl cellulose succinate, hydroxypropyl cellulose acetate succinate, hydroxyethyl methyl cellulose succinate, hydroxyethyl cellulose acetate succinate, hydroxypropyl methyl cellulose phthalate, hydroxyethyl methyl cellulose acetate succinate, hydroxyethyl methyl cellulose acetate phthalate, carboxyethyl cellulose, carboxymethyl cellulose, cellulose acetate phthalate, methyl cellulose acetate phthalate, ethyl cellulose acetate phthalate, hydroxypropyl cellulose acetate phthalate, hydroxypropyl methyl cellulose acetate phthalate, hydroxypropyl cellulose acetate phthalate succinate, hydroxypropyl methyl cellulose acetate succinate phthalate, hydroxypropyl methyl cellulose succinate phthalate, cellulose propionate phthalate, hydroxypropyl cellulose butyrate phthalate, cellulose acetate trimellitate, methyl cellulose acetate trimellitate, ethyl cellulose acetate trimellitate, hydroxypropyl cellulose acetate trimellitate, hydroxypropyl methyl cellulose acetate trimellitate, hydroxypropyl cellulose acetate trimellitate succinate, cellulose propionate trimellitate, cellulose butyrate trimellitate, cellulose acetate terephthalate, cellulose acetate isophthalate, cellulose acetate pyridinedicarboxylate, salicylic acid cellulose acetate, hydroxypropyl salicylic acid cellulose acetate, ethylbenzoic acid cellulose acetate, hydroxypropyl ethylbenzoic acid cellulose acetate, ethyl phthalic acid cellulose acetate, ethyl nicotinic acid cellulose acetate, and ethyl picolinic acid cellulose acetate.

REMARKS

As a preliminary matter, attention is directed to the Information Disclosure Statement (3 references), plus copies of each reference, submitted herewith. Please also note the Petition for Extension of Time (3 months) also submitted herewith.

The above amendments have been made to obviate a rejection under 35 USC §102(b) and §103(a), in accordance with a suggestion made by the Examiner. Claims 51 and 52 have both been incorporated into claims 1, 2, 3, and 4, the amendments being supported by the claims as originally filed. Sheets appended hereto and captioned as "Version Marked Up To Show Changes Made" show the exact nature of the emendations.

Claims 49-55 stand rejected under 35 U.S.C. §112 for indefiniteness, the Examiner having contended that the use of "cellulosic" renders the scope of these claims unascertainable. Applicants urge the Examiner to reconsider. The rejection is traversed on the basis that claim 13 is clear and understandable to those skilled in the art, and that is all that §112, second paragraph requires. See In re Borkowski, 164 USPQ 2d 642 where it was stated

The first sentence of the second paragraph of §112 is essentially a requirement for *precision* and *definiteness* of claim language. If the scope of subject matter embraced by a claim is clear, and if the applicant has not otherwise indicated that

he intends that claim to be of a different scope, then the claim does particularly point out and distinctly claim the subject matter which the applicant regards as his invention. [164 USPQ at 645-46; emphasis in original]

Per Borkowski, one skilled in the art must be able to tell with a reasonable degree of certainty whether his or her conduct is within or outside the scope of the claim, meaning the claims must clearly set out the boundaries of the claimed subject matter. In the instant application, it is submitted that those skilled in the art readily understand "cellulosic" on the basis, for example, that its definition can be looked up in a dictionary. Webster's Ninth New Collegiate Dictionary (Published by Merriam-Webster, Springfield, Massachusetts), for example, defines "cellulosic" as "a substance made from cellulose or a derivative of cellulose". Moreover, the application itself contains a comprehensive description and listing of specific cellulosic polymers, starting at page 94, line 16 and extending over to page 100. Surely, given the knowledge in the prior art (i.e., as evidenced, for example, by dictionary definitions) coupled with the extensive guidance and examples that Applicants have provided, one skilled in the art would have no problem understanding the metes and bounds of the property applicants have claimed. It is respectfully submitted that Applicants' are accordingly in compliance with §112, second paragraph, and it is respectfully submitted that the rejection should be withdrawn.

Claims 1, 17, 18, 49, 50 and 56 stand rejected under 35 USC 102(b) as being anticipated by Sikorski (WO 99/14204). Claims 2-10, 35-48, and 56-96 stand rejected for obviousness over Sikorski.

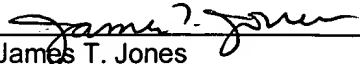
In response to the §102(b) rejection, and also to the §103(a) obviousness rejection, Applicants have amended generic claims 1, 2, 3 and 4 in accordance with the Examiner's suggestion by incorporating claims 51 and 52 therein. Applicants assume the Examiner's use of the term "generic" is synonymous with "independent". At page 3 of the Office Action, fourth and fifth lines from the bottom, Applicants further assume that the Examiner intended to refer to amending generic claims 1, 2, 3 and 4, rather than to refer to amending claim 1 only.

It is believed that the above amendments are fully in accord with the Examiner's suggestion. In respect of both the rejections under §102(b) and under §103(a), Applicants wish also to note that, while Applicants' invention relates to compositions comprising solid amorphous dispersions, Sikorski says nothing relating to dispersions of any kind. Applicants wish to note that this claim element, in addition to the amendments, distinguishes their invention over Sikorski even further, whether one is considering anticipation or obviousness.

In view of the foregoing comments and amendments, this case is believed to be in condition for allowance, and a Notice of Allowance is courteously solicited.

Respectfully submitted,

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James T. Jones  
Attorney for Applicant(s)  
Reg. No. 30,561

Pfizer Inc.  
Patent Department, Box 8260-1611  
Eastern Point Road  
Groton, CT 06340  
(860) 441-4903

VERSION MARKED UP TO SHOW CHANGES MADE

1. (Once Amended) A pharmaceutical composition comprising a solid amorphous dispersion of a cholesteryl ester transfer protein inhibitor and a concentration-enhancing polymer selected from the group consisting of hydroxypropyl methyl cellulose acetate, hydroxypropyl methyl cellulose, hydroxypropyl cellulose, methyl cellulose, hydroxyethyl methyl cellulose, hydroxyethyl cellulose acetate, hydroxyethyl ethyl cellulose, hydroxypropyl methyl cellulose acetate succinate, hydroxypropyl methyl cellulose succinate, hydroxypropyl cellulose acetate succinate, hydroxyethyl methyl cellulose succinate, hydroxyethyl cellulose acetate succinate, hydroxypropyl methyl cellulose phthalate, hydroxyethyl methyl cellulose acetate succinate, hydroxyethyl methyl cellulose acetate phthalate, carboxyethyl cellulose, carboxymethyl cellulose, cellulose acetate phthalate, methyl cellulose acetate phthalate, ethyl cellulose acetate phthalate, hydroxypropyl cellulose acetate phthalate, hydroxypropyl methyl cellulose acetate phthalate, hydroxypropyl cellulose acetate phthalate succinate, hydroxypropyl methyl cellulose acetate succinate phthalate, hydroxypropyl methyl cellulose succinate phthalate, cellulose propionate phthalate, hydroxypropyl cellulose butyrate phthalate, cellulose acetate trimellitate, methyl cellulose acetate trimellitate, ethyl cellulose acetate trimellitate, hydroxypropyl cellulose acetate trimellitate, hydroxypropyl methyl cellulose acetate trimellitate, hydroxypropyl cellulose acetate trimellitate succinate, cellulose propionate trimellitate, cellulose butyrate trimellitate, cellulose acetate terephthalate, cellulose acetate isophthalate, cellulose acetate pyridinedicarboxylate, salicylic acid cellulose acetate, hydroxypropyl salicylic acid cellulose acetate, ethylbenzoic acid cellulose acetate, hydroxypropyl ethylbenzoic acid cellulose acetate, ethyl phthalic acid cellulose acetate, ethyl nicotinic acid cellulose acetate, and ethyl picolinic acid cellulose acetate.

2. (Once Amended) A pharmaceutical composition comprising a solid amorphous dispersion of a cholesteryl ester transfer protein inhibitor and a concentration-enhancing polymer, said cholesteryl ester transfer protein inhibitor having a solubility in aqueous solution, in the absence of said concentration-enhancing polymer, of less than 10  $\mu$ g/ml at any pH of from 1 to 8, said concentration-enhancing polymer selected from the group consisting of hydroxypropyl methyl cellulose acetate, hydroxypropyl methyl cellulose, hydroxypropyl cellulose, methyl cellulose, hydroxyethyl methyl cellulose, hydroxyethyl cellulose acetate, hydroxyethyl ethyl cellulose, hydroxypropyl methyl cellulose acetate succinate, hydroxypropyl methyl cellulose succinate, hydroxypropyl cellulose acetate succinate, hydroxyethyl methyl cellulose succinate, hydroxyethyl cellulose acetate

succinate, hydroxypropyl methyl cellulose phthalate, hydroxyethyl methyl cellulose acetate succinate, hydroxyethyl methyl cellulose acetate phthalate, carboxyethyl cellulose, carboxymethyl cellulose, cellulose acetate phthalate, methyl cellulose acetate phthalate, ethyl cellulose acetate phthalate, hydroxypropyl cellulose acetate phthalate, hydroxypropyl methyl cellulose acetate phthalate, hydroxypropyl cellulose acetate phthalate succinate, hydroxypropyl methyl cellulose acetate succinate phthalate, hydroxypropyl methyl cellulose succinate phthalate, cellulose propionate phthalate, hydroxypropyl cellulose butyrate phthalate, cellulose acetate trimellitate, methyl cellulose acetate trimellitate, ethyl cellulose acetate trimellitate, hydroxypropyl cellulose acetate trimellitate, hydroxypropyl methyl cellulose acetate trimellitate, hydroxypropyl cellulose acetate trimellitate succinate, cellulose propionate trimellitate, cellulose butyrate trimellitate, cellulose acetate terephthalate, cellulose acetate isophthalate, cellulose acetate pyridinedicarboxylate, salicylic acid cellulose acetate, hydroxypropyl salicylic acid cellulose acetate, ethylbenzoic acid cellulose acetate, hydroxypropyl ethylbenzoic acid cellulose acetate, ethyl phthalic acid cellulose acetate, ethyl nicotinic acid cellulose acetate, and ethyl picolinic acid cellulose acetate.

3. (Once Amended) A pharmaceutical composition comprising a solid amorphous dispersion of a cholesteryl ester transfer protein inhibitor and a concentration-enhancing polymer, said composition providing a maximum concentration of said cholesteryl ester transfer protein inhibitor in a use environment that is at least 10-fold the maximum concentration provided by a control composition comprising an equivalent amount of said cholesteryl ester transfer protein inhibitor and free from said concentration-enhancing polymer, said concentration-enhancing polymer selected from the group consisting of hydroxypropyl methyl cellulose acetate, hydroxypropyl methyl cellulose, hydroxypropyl cellulose, methyl cellulose, hydroxyethyl methyl cellulose, hydroxyethyl cellulose acetate, hydroxyethyl ethyl cellulose, hydroxypropyl methyl cellulose acetate succinate, hydroxypropyl methyl cellulose succinate, hydroxypropyl cellulose acetate succinate, hydroxyethyl methyl cellulose succinate, hydroxyethyl cellulose acetate succinate, hydroxypropyl methyl cellulose phthalate, hydroxyethyl methyl cellulose acetate succinate, hydroxyethyl methyl cellulose acetate phthalate, carboxyethyl cellulose, carboxymethyl cellulose, cellulose acetate phthalate, methyl cellulose acetate phthalate, ethyl cellulose acetate phthalate, hydroxypropyl cellulose acetate phthalate, hydroxypropyl methyl cellulose acetate phthalate, hydroxypropyl cellulose acetate phthalate succinate, hydroxypropyl methyl cellulose acetate succinate phthalate, hydroxypropyl methyl cellulose succinate phthalate, cellulose propionate phthalate, hydroxypropyl cellulose butyrate

phthalate, cellulose acetate trimellitate, methyl cellulose acetate trimellitate, ethyl cellulose acetate trimellitate, hydroxypropyl cellulose acetate trimellitate, hydroxypropyl methyl cellulose acetate trimellitate, hydroxypropyl cellulose acetate trimellitate succinate, cellulose propionate trimellitate, cellulose butyrate trimellitate, cellulose acetate terephthalate, cellulose acetate isophthalate, cellulose acetate pyridinedicarboxylate, salicylic acid cellulose acetate, hydroxypropyl salicylic acid cellulose acetate, ethylbenzoic acid cellulose acetate, hydroxypropyl ethylbenzoic acid cellulose acetate, ethyl phthalic acid cellulose acetate, ethyl nicotinic acid cellulose acetate, and ethyl picolinic acid cellulose acetate.

4. (Once Amended) A pharmaceutical composition comprising a solid amorphous dispersion of a cholesteryl ester transfer protein inhibitor and a polymer, said composition providing a relative bioavailability that is at least 4 relative to a control composition comprising an equivalent amount of said cholesteryl ester transfer protein inhibitor and free from said polymer, said polymer selected from the group consisting of hydroxypropyl methyl cellulose acetate, hydroxypropyl methyl cellulose, hydroxypropyl cellulose, methyl cellulose, hydroxyethyl methyl cellulose, hydroxyethyl cellulose acetate, hydroxyethyl ethyl cellulose, hydroxypropyl methyl cellulose acetate succinate, hydroxypropyl methyl cellulose succinate, hydroxypropyl cellulose acetate succinate, hydroxyethyl methyl cellulose succinate, hydroxyethyl cellulose acetate succinate, hydroxypropyl methyl cellulose phthalate, hydroxyethyl methyl cellulose acetate succinate, hydroxyethyl methyl cellulose acetate phthalate, carboxyethyl cellulose, carboxymethyl cellulose, cellulose acetate phthalate, methyl cellulose acetate phthalate, ethyl cellulose acetate phthalate, hydroxypropyl cellulose acetate phthalate, hydroxypropyl methyl cellulose acetate phthalate, hydroxypropyl cellulose acetate phthalate succinate, hydroxypropyl methyl cellulose acetate succinate phthalate, hydroxypropyl methyl cellulose succinate phthalate, cellulose propionate phthalate, hydroxypropyl cellulose butyrate phthalate, cellulose acetate trimellitate, methyl cellulose acetate trimellitate, ethyl cellulose acetate trimellitate, hydroxypropyl cellulose acetate trimellitate, hydroxypropyl methyl cellulose acetate trimellitate, hydroxypropyl cellulose acetate trimellitate succinate, cellulose propionate trimellitate, cellulose butyrate trimellitate, cellulose acetate terephthalate, cellulose acetate isophthalate, cellulose acetate pyridinedicarboxylate, salicylic acid cellulose acetate, hydroxypropyl salicylic acid cellulose acetate, ethylbenzoic acid cellulose acetate, hydroxypropyl ethylbenzoic acid cellulose acetate, ethyl phthalic acid cellulose acetate, ethyl nicotinic acid cellulose acetate, and ethyl picolinic acid cellulose acetate.